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# 510(k) Summary
## Datascope ViewPoint™ Central Monitoring System

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- **Date Prepared:** May 16, 2001

**Name of the device:**

- Trade/Proprietary Name: ViewPoint™ Central Monitoring System

Please note that during the product development process, the device was also referred to as "ViewPoint™", "Enterprise" and "Enterprise Central Station" (or "ESC") and these names will be found in some of the supporting documentation included in this submission.

- Common Name: System, Network and Communication, Physiological Monitors

- Classification:

| C.F.R Section | Classification Name | Product Code(s) | Regulatory Class |
|---|---|---|---|
| None | System, Network and Communication, Physiological Monitors | MSX | III |

## Legally Marketed Predicate Devices:

This submission compares the performance specifications and functionality of the ViewPoint Central Monitoring System with those of two (2) similar devices: VitalCom Inc. (VCOM, IRVS, RVS) Central Monitoring Station (K962473) and Hewlett-Packard Company CentralVue Software for Model M3150A (K993171), the legally marketed predicate devices. The functionality of the ViewPoint Monitoring System is identical to that of the VitalCom Inc. (VCOM, IRVS, RVS) Central Monitoring Station and Hewlett-Packard Company CentralVue Software for Model M3150A.

## Description:

The Datascope Corp. ViewPoint Central Monitoring System can display, record and recall clinical data such as ECG waveforms, Heart Rate derived from selected source ($SpO_2$, ECG, IBP and NIBP), $SpO_2$ level, ST Segment (adult and pediatric only), Arrhythmia (adult and pediatric only), Blood Pressure (both Invasive and Non-Invasive), Respiration Rate (derived from ECG or $CO_2$), $CO_2$, Temperature and alarms. It also monitors status for up to 8 patients. The clinical data is derived from Passport 2 Vital signs monitor (K993531) or other Datascope compatible physiological monitor(s) connected to the Central Monitoring System via the ViewPoint Patient Network.

## Statement of Intended Use:

## Indications for use: ViewPoint™ Central Monitoring System

The indications for use for the ViewPoint Central Monitoring System include:

- Viewing real time patient clinical and demographic data
- Graphical and numeric trending of clinical data
- Storing and printing of clinical and demographic data
- Setting independent alarm limits for data sent by the bedside monitor.

The clinical data is obtained from one or more compatible physiological monitors and includes: ECG waveforms, Invasive and Non-Invasive Blood Pressure, Blood Oxygenation (SpO2), Heart Rate, Respiration Rate, Temperature, CO2 inspired and end tidal, Ventricular Arrhythmia analysis and ST Segment analysis.

The ViewPoint Central Monitoring System is intended for use in a fixed location, in the health care facility setting , as a central viewing station. The ViewPoint Central Monitoring System is not intended to be directly connected to the patient at any time, or installed in a patient's vicinity.

## Comparison of Technological Characteristics

The ViewPoint Central Monitoring System is substantially equivalent to a combination of systems currently marketed by Hewlett-Packard Company and VitalCom Inc. The indications for use and technological characteristics of the new device are the same as those of the legally marketed predicate devices.

## Testing:

The ViewPoint Central Monitoring System has been subject to extensive safety and performance testing. Final testing for the device included various performance tests designed to ensure that the product meets all functional requirements and performance specifications. Where applicable the safety testing has been performed by third party agencies. The device has also been tested to assure compliance to the requirements of various published standards, including ANSI/AAMI EC13 (applicable portions), IEC 60601-1-4 (1996-05), EN 55022:1998, EN 55024:1998, EN 61000-3-3:1995, EN 61000-4-2:1995 with Amendment 1(A1:1998), EN 61000-4-4:1995, EN 61000-4-5:1995, EN 61000-4-6:1996, EN 61000-4-8:1993, EN 61000-4-11:1994, EN 61000-3-2:1995, EN 61000-4-3:1998 and CAN/CSA C22.2 No. 950-95.

In conclusion, the ViewPoint Central Monitoring System is substantially equivalent to the predicate devices and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Mr. Russell Olsen
Datascope Corp.
Patient Monitoring Division
800 MacArthur Blvd.
Mahwah, NJ 07430-0619

Re: K011540
Trade Name: ViewPoint™ Central Monitoring System
Regulation Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: May 17, 2001
Received: May 18, 2001

Dear Mr. Olsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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**Indications for use:** **ViewPoint™ Central Monitoring System**

The indications for use for the ViewPoint™ Central Monitoring System include:

(a) Viewing real time patient clinical and demographic data
(b) Graphical and numeric trending of clinical data
(c) Storing and printing of clinical and demographic data
(d) Setting independent alarm limits for data sent by the bedside monitor.

The clinical data displayed by the ViewPoint™ Central Monitoring System is obtained from one or more Datascope compatible physiological monitors and includes: ECG waveforms, Invasive and Non-Invasive Blood Pressure, Blood Oxygenation (SpO2), Heart Rate, Respiration Rate, Temperature, CO2 inspired and end tidal, Ventricular Arrhythmia analysis and ST Segment analysis.

The ViewPoint™ Central Station System is intended for use in a fixed location, in the health care facility setting , as a central viewing station. The ViewPoint™ Central Monitoring System is not intended to be directly connected to the patient at any time, or installed in a patient's vicinity.

Division of Cardiovascular & Respiratory Devices
510(k) Number K011540

PRESCRIPTION USE